

REMARKS

Claims 1-36 are pending in the application. Claims 1-7 and 22-36 are rejected. Claims 8-21 are withdrawn from consideration because of improper multiple dependency. Applicant has amended claims 8-10, 12, 13, 16-18 and 20 in order to remove the basis for improper multiple dependency. All of these claims now should be allowable for their direct or indirect dependence from claim 1. Claims 25 and 28 have been amended in order to provide a proper dependency, so that the features of the invention are accurately recited. In addition, claim 37 (a combination of claims 22, 26 and 27), claim 38 (a combination of claims 23, 26 and 27), and claim 39 (a combination of claims 23, 26, 28 and 29) have been added.

Claim Objections

Claims 8-21 are objected to as being in improper form 1 because multiple dependent claims depend from multiple dependent claims. This rejection is traversed on the basis of the amendments made to claims 8-10, 12, 13, 16-18 and 20, which now depend only from claim 1. All of these claims now should be allowable for their direct or indirect dependence from claim 1, which is patentable over the prior art as demonstrated below.

Claim Rejections - 35 U.S.C. § 112

Claim 25 is rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner notes that claim 25 appears to conflict with claim 24. Applicant has amended claim 25 to make it depend from claim 22. Thus, this rejection should be overcome.

Claim Rejection - 35 U.S.C. § 102

Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cornacchia et al (5,472,403). This rejection is traversed for at least the following reasons.

The object of the present invention is to provide a contrast agent injection system which is safe for the patient and delivers a desired quantity of contrast agent from a first injector (1) followed automatically by a quantity of rinsing fluid from a second injector (2). In order to

achieve this goal, the invention includes a control device (16) that monitors the quantity of contrast agent fed to the patient's body through a tube (7). The control device then automatically controls the delivery of the rinsing fluid after the delivery of the contrast agent has been terminated. These two distinguishing features are recited in rejected claim 1.

Given this structure, an additional feature of the invention is that it can enable the subsequent retrofitting of previously used single-piston injectors to form a dual-piston system and to allow actuation of a second or additional injector without direct electronic connection to the first injector.

Cornacchia

USP 5,472,403 (Cornacchia) shows an automatic injection device comprising two syringes (2, 4). Each of these syringes is driven by a motor, the motor receiving an activation signal from a computer controller, which initiates the injection sequence upon receipt of a trigger signal that is provided by a separate seizure detection computer 62 in response to activation by the patient, activation by medical personal or by SDC detection of a seizure (see for example col. 5, lines 1-13).

Cornacchia discloses a very complicated apparatus which, according to figure 3 and its corresponding description, includes a motor control logic 44 for controlling motors 10 and 12 and depends on a computer 40 and other electronic equipment. According to Cornacchia beginning at column 4, line 13, the computer 40 is connected to an interface using a control box consisting of three boards, as explained beginning at column 4, line 19. For the control of the injection device, the computer needs information from potentiometers and switches (column 4, line 51 et seq.). In sum, this known apparatus needs software (column 4, line 56) for its automatic operation on a programmed basis. However, the injection device according to figure 1 and figure 3 of Cornacchia does not use any detector or sensor for monitoring any fluid flow in connector 22/25/26. As is clear from the description at col. 7, lines 31-51, the initiation of rinsing solution syringe 4 is dependent on the software instead of the monitoring of fluid flow from syringe 2.

By contrast, according to claim 1 of the present application, a control device (16) monitors the delivery of the contrast agent through a tube section (7) and automatically controls the delivery of the fluid by the second injector after the delivery of the contrast agent has been terminated. The subject matter of claim 1 is not concerned with the pure sequential infusion of fluids. Instead, it is concerned with the control of the infusion of the first injector and starting the control of the second injector depending on a monitoring of the fluid flow from the first injector.

Clearly, the claim is not anticipated by the teachings of Cornacchia and this rejection must be withdrawn.

Claim Rejections - 35 U.S.C. § 103

Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Cornacchia in view of Calderon (4,867,742). This rejection is traversed for at least the following reasons.

Calderon

The Examiner looks to Calderon solely for its teaching of a control of flow rate using a feedback loop. The deficiencies of Cornacchia are not remedied by Calderon. There is no teaching or suggestion in either reference of a system or device for monitoring the delivery of a contrast agent from a first injector and the automatic control of the delivery of a rinsing fluid from a second injector, as claimed. The motivation suggested by the examiner reflects an improper use of hindsight.

Thus, this rejection is overcome.

Claim 22-24 and 26-31 are rejected as being unpatentable over Cornacchia in view of Yerlikaya (US 5256155). This rejection is traversed for at least the following reasons.

As defined in independent claims 22 and 23, the injection system according to the present invention is provided with a sensing device or detection device 14/20 for (1) detecting the fluid flow within a subordinate tube section or (2) an optical signal from the first injector as a result of the interruption of the injection of the first injector. The sensing or detecting device 14/20 is

connected to a control device 16 which, depending on the signal of the sensing or detection device, starts the injection of the second injector.

Beginning at page 3, line 6, the present application teaches that the second injector is **not directly connected** to the first injector so that the activation of the second injector is **not directly dependent** on the operation of the first injector. This is emphasized by the word “independent” in claims 22 and 23.

Yerlikaya

The deficiencies of Cornacchia already have been identified, and its operation as a preprogrammed device noted as a distinction over the invention. The patent to Yerlikaya does not remedy the deficiencies of Cornacchia and is not even pertinent to the subject matter of the present invention or Cornacchia. Yerlikaya refers to a “drop detector circuit for medical drop chambers which are used in medical devices”. The purpose of such drop chamber is not to register fluid flow and sense an interruption in fluid flow, as claimed, but instead to count the number of drops falling in a given time period (column 1, line 16 et seq.):

“Such drop chambers are used, for example in gravity-driven or pump-driven infusion systems.

Devices are known in the art for automatically sensing the drops in a chamber. These may, for example, be connected to circuits that can compute and display the flow rate or to alarms that indicate when the flow rate is too high or too low.” (column 1, line 18 et seq.).

Clearly, Yerlikaya does not show any detector or sensor for detecting and interrupting a fluid flow within a tube and for outputting a signal to a control device which control device is provided for activating a second injector.

Not only is Yerlikaya deficient in teaching claimed structures, the device of Yerlikaya is not even suitable to be used in connection with Cornacchia, and certainly not for achievement of the features of the present invention for at least the following reasons:

According to column 3, line 33 et seq. the known drop detector 20 includes a drop chamber 22 which has to be provided in an upright position (column 3, line 39). With reference to column 3, line 62 et seq., the Yerlikaya device cannot work at tilted angles, as would be necessary for the application taught in Cornacchia. Furthermore the Yerlikaya device only works in connection with counting of drops, as explained at column 4, line 1 et seq., and could not work with a flow of fluid.

“The result of having two IRLEDs 38 opposite a single photodiode 40 is to create a triangular optical path 41 that can be broken by a drop passing through any portion of...”

Moreover, there is no basis for concluding that a combination of Cornacchia and Yerlikaya would be suggested to a person skilled in the art. The technical challenges to mix a liquid flow device with a device as in Yerlikaya that teaches the use of optical sensors to detect the flow of drops in a vertical medical device, could be met only with the improper application of hindsight based on the applicant’s own teachings.

Indeed, even if the two references were combined, they would not meet the claimed invention. The present invention is not related to infusion devices where the infusion is given in form of drops. In other words the device according to Yerlikaya can not be used in connection with syringes for the introduction of radionuclide or the injection of a saline solution for flushing the intravenous tubing.

In sum, neither Cornacchia nor Yerlikaya or a combination of both references would lead one skilled in the art to consider claims 22 and 23, which claim the use of a sensing or detecting device for sensing the fluid flow within a tube section or for sensing an optical signal from that first injector for activating the control device 16 to activate the second injector, to be obvious.

Accordingly, the rejection should be withdrawn.

Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Cornacchia in view of Calderon (4,867,742) and further in view of Yerlikaya. This rejection is traversed for at least the following reasons.

Applicant respectfully relies on the above noted deficiencies of the prior art teachings, their lack of combinability and their distinctly different approaches and purposes to submit that the prior art does not render the claimed invention obvious.

Accordingly, the rejection should be withdrawn.

Claim 5 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Cornacchia in view of Calderon (4,867,742) and further in view of Krivitski et al (5,685,989). This rejection is traversed for at least the following reasons.

Applicant respectfully relies on the above noted deficiencies of the prior art teachings, their lack of combinability and their distinctly different approaches and purposes to submit that the prior art does not render the claimed invention obvious.

The Examiner admits that none of the references utilize sound to detect flow and looks to Krivitski et al for such teaching of a detection of fluid flow using sound. However, the Examiner cannot remedy the deficiencies of the two base references with any teaching of Krivitski et al. There is no basis for a teaching or suggestion that a flow sensor of Krivitski et al would be used as an activator of a second injection unit, since this begs the question of whether there is any suggestion of controlling a second unit on the basis of a detection of a first unit at all. Thus, the claim should be considered patentable.

Accordingly, the rejection should be withdrawn.

Claim 25 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Cornacchia in view of Yerlikaya and further in view of Krivitski et al (5,685,989). This rejection is traversed for at least the following reasons.

Applicant respectfully relies on the above noted deficiencies of the prior art teachings, their lack of combinability and their distinctly different approaches and purposes to submit that the prior art does not render the claimed invention obvious.

The Examiner admits that none of the references utilize sound to detect flow and looks to Krivitski et al for such teaching of a detection of fluid flow using sound. However, the Examiner cannot remedy the deficiencies of the two base references with any teaching of Krivitski et al.

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There is no basis for a teaching or suggestion that a flow sensor of Krivitski et al would be used as an activator of a second injection unit, since this begs the question of whether there is any suggestion of controlling a second unit on the basis of a detection of a first unit at all. Thus, the claim should be considered patentable.

Accordingly, the rejection should be withdrawn.

Claims 32 and 33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cornacchia and Yerlikaya and further in view of Wilson et al (WO 96/32887). This rejection is traversed for at least the following reasons.

Applicant respectfully relies on the above noted deficiencies of the prior art teachings in Cornacchia and Yerlikaya, their lack of combinability and their distinctly different approaches and purposes to submit that the prior art does not render the claimed invention obvious.

The Examiner admits that neither references utilizes fill valves on the injectors and looks to Wilson et al for such teaching of such valves. However, the Examiner cannot remedy the deficiencies of the two base references with any teaching of Wilson et al. There is no basis for a teaching or suggestion that reservoir larger than a single syringe could be used and nothing in Wilson et al to support such suggestion, or otherwise remedy the deficiencies of Cornacchia and Yerlikaya. Thus, the claim should be considered patentable.

Accordingly, the rejection should be withdrawn.

Claim 35 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Cornacchia and Yerlikaya and further in view of Wallis (5,236,417). This rejection is traversed for at least the following reasons.

Applicant respectfully relies on the above noted deficiencies of the prior art teachings in Cornacchia and Yerlikaya, their lack of combinability and their distinctly different approaches and purposes to submit that the prior art does not render the claimed invention obvious.

The Examiner admits that neither references utilizes interchangeable syringes and looks to Wallis for such teaching on the basis of simple luer connections to fit standard syringes. However, the Examiner cannot remedy the deficiencies of the two base references with any

teaching of Wallis. There is no basis in Wallis for a teaching or suggestion that the use of a sensing or detecting device for sensing the fluid flow within a tube section or for sensing an optical signal from that first injector for activating the control device to activate the second injector, is obvious. Thus, the claim should be considered patentable.

Accordingly, the rejection should be withdrawn.

Claim 36 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Cornacchia and Yerlikaya and Wallis, further in view of Segal (6,402,207). This rejection is traversed for at least the following reasons..

Applicant respectfully relies on the above noted deficiencies of the prior art teachings in Cornacchia, Wallis and Yerlikaya, their lack of combinability and their distinctly different approaches and purposes to submit that the prior art does not render the claimed invention obvious.

The Examiner admits that none of the three primary references utilizes specific openings for different syringes, and looks to Segal for such teaching of systems for insuring that fluid containers are not used with an incorrect fluid path. However, the Examiner cannot remedy the deficiencies of the three base references with any teaching of Segal. There is no basis in Segal for a teaching or suggestion that the use of a sensing or detecting device for sensing the fluid flow within a tube section or for sensing an optical signal from that first injector for activating the control device to activate the second injector, is obvious. Thus, the claim should be considered patentable.

Accordingly, the rejection should be withdrawn.

New Claims

The new claims 37-39 are based on a combination of claims 22 or 23 with other dependent claims and would be patentable for the reasons already given.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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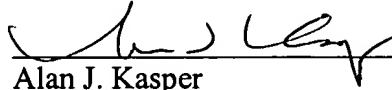
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